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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,055	08/21/2003	Douglas A. Devens JR.	1001.2346101	6549
11050 7590 12/22/2010 SEAGER, TUFTE & WICKHEM, LLC 1221 Nicollet Avenue Suite 800 Minneapolis, MN 55403				
EXAMINER				
CAMPBELL, VICTORIA P				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
12/22/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/645,055

**Applicant(s)**

DEVENS ET AL.

**Examiner**

VICTORIA P. CAMPBELL

**Art Unit**

3763

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-942)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is the initial Office Action following the third Request for Continued Examination based on the 10/645055 application filed August 21, 2003. Claims 49-68 as newly presented November 18, 2010 are currently pending and considered below.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 18, 2010 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 49-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Regarding independent claims 49, 60, and 68, the claims contain either the limitation "wherein the outer layer has a lesser thickness in the body portion than in the proximal waist" (Claims 49 and 68) or the limitation "wherein the outer layer has a lesser thickness in the body portion than in the distal waist" (Claim 60). The examiner notes that there is no discussion of the thickness of the outer layer of the balloon in the specification. If applicant is relying upon the drawings (specifically elected Figure 2) to support this limitation, the examiner notes that, as no mention that the figures are drawn to scale is given, the drawings can not be relied upon to support the above limitations. Claims 50-59 and 61-67 are rejected for their dependence upon a rejected base claim.
5. Regarding claims 50 and 61, the claims contain the limitation "wherein a sum of the thicknesses of the inner and outer layers is constant over the length of the balloon." The examiner notes that the specification lacks support for this limitation and only supports the much broader limitation of the sum being "substantially constant" (Page 5, line 7 of the instant specification). In the case that applicant was relying upon this statement to support the claim limitations described above (in the manner that if the overall thickness  $T$  is constant, then  $T-T_{IB}$  must be less than  $T-T_{IW}$ ), with  $T$  being only substantially constant, the equations fail as  $T$  is no longer a constant value.
6. Regarding claims 51 and 62, the claims contain the limitation that "the inner and outer layers each have a constant thickness in the body portion, in the proximal and distal waists, and in the proximal and distal cones." However, the examiner can only find support in the specification for the constant thickness in the proximal (Page 2, lines 18-20) and distal (Page 2, lines 21-22) cones. For the constant thickness in the waist

and body portions, applicant appears to be depending on elected Figure 2 for support. As in paragraph 4 above, the examiner notes that, as no mention that the figures are drawn to scale is given, the drawings can not be relied upon to support the above limitations.

7. Regarding claims 52 and 63, the specification lacks support for the recited limitation that "the inner and outer layers each have respective thickness that vary only in the transitions between adjacent sections along the length of the balloon." There is no mention in the specification of transitions or any change of thickness taking place at such a location. To support this limitation, applicant appears to be depending on elected Figure 2 for support. As in paragraphs 4 and 6 above, the examiner notes that, as no mention that the figures are drawn to scale is given, the drawings can not be relied upon to support the above limitations.

### ***Response to Arguments***

8. In response to applicant's request that the examiner confirm that the specification as filed is proper and not the specification that was wrongly published in the Pre-Grant Publication of this application, the examiner confirms the specification as filed and considered by the examiner contains a cover sheet, 18 pages of text, an abstract, 5 pages of originally filed claims, and 3 pages of originally filed drawings, all dated August 21, 2003.

9. Regarding applicant's new claims, see the above action on the merits.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Friday, 7-3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763